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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,198	01/14/2002	Wayne P. Fitzmaurice	N1328-004	7489
32905	7590	12/05/2003	EXAMINER	
JONDLE & ASSOCIATES P.C. 9085 EAST MINERAL CIRCLE SUITE 200 CENTENNIAL, CO 80112			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,198	FITZMAURICE, WAYNE P.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10, in the response filed 22 September 2003 is acknowledged.
2. Claims 11-18 are herein withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse the response filed 22 September 2003.
3. This application contains claims 11-18 drawn to an invention nonelected ^{without} _{in} traverse the response filed 22 September 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. § 121 is acknowledged. However, the nonprovisional application(s) upon which priority is claimed fail(s) to provide adequate support under 35 U.S.C. § 112 for claims 1-10 of this application. U.S. Patent Applications 09/232,170, filed 15 January 1999 and 09/008,186, filed 16 January 1999, failed to provide an adequate written description support under 35 U.S.C. § 112, first paragraph, for claims 1-10.
5. In the first line of the specification, the priority information requires amendment to indicate that parent application 09/353,787 has now issued as U.S. Patent 6,344,597, and that application 09/232,170 is now abandoned. Appropriate correction is required.

Claim Objections

6. Claims 1, 6 and 8 are objected to because of the following informalities:

The specific epitaphs "Excelsior" and "Benthamiana" should not be capitalized as a matter of form in claim 1.

At claims 6 and 8, "Tissue culture" should read -- A tissue culture --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1, 2, 5, 6 and 9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is deemed indefinite because it is unclear if the instant claim is directed to a seed or to a plant. Consequently claims 2 and 6 are also deemed indefinite because it is unclear what the metes and bounds of claim 1 are.

At claim 9, line 1, the phrase "having essentially all of" is indefinite because it is unclear from the instant specification what the metes and bound of "essentially all" encompasses. Amending said phrase to read -- having all of -- would obviate this rejection.

At claim 9, line 3, the phrase "or protoplasts or calli derived therefrom" is indefinite because it is unclear what the metes and bounds of "derived therefrom" encompasses. In addition, said phrase does not appear to be encompassed by the

listing of species and does not appear to further limit the "Tissue culture of regenerable cells" at claim 8.

9. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 7 and 10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a *Nicotiana* plant regenerated from a tissue culture produced from seed or the plant or parts of the *Nicotiana* interspecific hybrid deposited under ATCC Accession No. PTA-323.

Applicant describes the *Nicotiana* interspecific hybrid deposited under ATCC Accession No. PTA-323.

Applicant does not describe somatic variants of the *Nicotiana* interspecific hybrid deposited under ATCC Accession No. PTA-323 that would be produced by regeneration from a tissue culture.

Hence, it is unclear that Applicant has adequately described the invention as broadly claimed.

Amending the instant claims to recite -- having all of the physiological and morphological characteristics of the *Nicotiana* plant of claim 2 -- would obviate this rejection.

11. Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability (page 23 of the specification).

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed

upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

Claims 7 and 10 of additionally rejected as not adequately enabled as directed to a myriad of somoclonal variant plants regenerated from a tissue culture of the *Nicotiana* interspecific hybrid deposited under ATCC Accession No. PTA-323, of which Applicant has not taught one of skill in the art how to make and use such somoclonal variant plants. The *Nicotiana* interspecific hybrid deposited under ATCC Accession No. PTA-

323 appears to have unique characteristics that are the consequence of the full genetic makeup of said hybrid. Thus without specific guidance on how to make and use the myriad of possible somoclonal variant plants regenerated from a tissue culture, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to produce and fully determine a use of such somoclonal variant plants. Amending claims 7 and 10 as suggested above would obviate this part of the rejection.

Double Patenting

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

In the instant rejection claim 1 of the instant application is read as being directed to a hybrid seed.

13. Claim 1 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 26 of prior U.S. Patent No. 6,344,597. This is a double patenting rejection.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

In the instant rejection, claim 1 of the instant application is read as being directed to other than just a hybrid seed, see the rejection above.

15. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No.

6,344,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the seed of claim 26 of the '597 render obvious a plant produced therefrom, tissue culture produced therefrom and plants regenerated from said tissue culture. The Examiner notes that no requirement for Election/Restriction was made in parent application 09/353,787, hence there is not reason that Applicant was prevented from presenting the instant claims in said parent application.

Conclusion


16. Claims 1-10 are free of the prior art, which neither teaches nor fairly suggests the interspecific *Nicotiana* hybrid deposited under ATCC Accession No. PTA-323.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539, **(571) 272-0799 after 6 January 2004**. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218, **(571) 272-0804 after 6 January 2004**. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.


AA 1638

David H. Kruse, Ph.D.
25 November 2003